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EXAMINER	
MACIAS, CHANDA L	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,832	MORRIS ET AL.	
	Examiner	Art Unit	
	Chanda L. Macias	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed July 22, 2002, is acknowledged and has been entered.

2. Claims 1-19 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-1176. Claims 1-4, insofar as the claims are drawn to a recombinant nucleic acid molecule, a vector comprising said nucleic acid molecule, and a host cell comprising said nucleic acid molecule or said vector, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified, for example, in class 535, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325, respectively.

Note: If Applicant elects any of the inventions of Groups 1-1176, Applicant must do so by specifically identifying either: (a) any one of the sequences identified as SEQ ID NOs: 1-952 set forth in Table 1 or Table 2; (b) any one of the mouse sequences (genomic, mRNA, and coding) set froth in Tables 3-112; or (b) any one of the human sequences (genomic, mRNA, and coding) set froth in Tables 3-112.

For example, if Applicant were to elect the invention of Group 953, Applicant would identify the elected invention by selecting the mouse genomic, mRNA, and coding sequences of SEQ ID NOs: 953-955 (i.e., the sequences listed in Table 3 as corresponding to the mouse *Fscn1* gene).

Groups 1177-2352. Claim 5, insofar as the claim is drawn to a recombinant protein comprising an amino acid sequences encoded by a nucleic acid sequence, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified, for example, in class 530, subclass 350.

Note: If Applicant elects any of the inventions of Groups 1177-2352, Applicant must do so by specifically identifying either: (a) any one of the sequences identified as SEQ ID NOs: 1-952 set forth in Table 1 or Table 2; (b) any one of the mouse sequences (genomic, mRNA, and coding) set froth in Tables 3-112; or (b) any one of the human sequences (genomic, mRNA, and coding) set froth in Tables 3-112.

Groups 2353-3528. Claims 6 and 7, insofar as the claims are drawn to a method for screening drug candidates, said method comprising providing a cell that expresses a nucleic acid molecule, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified, for example, in class 435, subclass 6.

Note: If Applicant elects any of the inventions of Groups 2353-3528, Applicant must do so by specifically identifying either: (a) any one of the sequences identified as SEQ ID NOs: 1-952 set forth in Table 1 or Table 2; (b) any one of the mouse sequences (genomic, mRNA, and coding) set froth in Tables 3-112; or (b) any one of the human sequences (genomic, mRNA, and coding) set froth in Tables 3-112.

Groups 3529-4704. Claim 8, insofar as the claim is drawn to a method for screening bioactive agents, said method comprising determining binding of a candidate bioactive agent with a polypeptide encoded by a nucleic acid molecule, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified, for example, in class 436, subclass 501.

Note: If Applicant elects any of the inventions of Groups 3529-4704, Applicant must do so by specifically identifying either: (a) any one of the sequences identified as SEQ ID NOs: 1-952 set forth in Table 1 or Table 2; (b) any one of the mouse sequences (genomic, mRNA, and coding) set froth in Tables 3-112; or (b) any one of the human sequences (genomic, mRNA, and coding) set froth in Tables 3-112.

Groups 4705-5880. Claim 9, insofar as the claim is drawn to a method for screening bioactive agents, said method comprising determining the effect of a candidate bioactive agent upon the bioactivity of a polypeptide encoded by a nucleic acid molecule, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified, for example, in class 435, subclass 183.

Note: If Applicant elects any of the inventions of Groups 4705-5881, Applicant must do so by specifically identifying either: (a) any one of the sequences identified as SEQ ID NOs: 1-952 set forth in Table 1 or Table 2; (b) any one of the mouse

sequences (genomic, mRNA, and coding) set froth in Tables 3-112; or (b) any one of the human sequences (genomic, mRNA, and coding) set froth in Tables 3-112.

Groups 5881-7056. Claim 10, insofar as the claims are drawn to a method for evaluating the effect of a drug administered to a patient, said method comprising determining the alteration in the expression or activation of a gene, wherein said gene comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified, for example, in class 435, subclass 6.

Note: If Applicant elects any of the inventions of Groups 5882-7057, Applicant must do so by specifically identifying either: (a) any one of the sequences identified as SEQ ID NOs: 1-952 set forth in Table 1 or Table 2; (b) any one of the mouse sequences (genomic, mRNA, and coding) set froth in Tables 3-112; or (b) any one of the human sequences (genomic, mRNA, and coding) set froth in Tables 3-112.

Group 7057. Claim 11, drawn to a method for diagnosing carcinoma, said method comprising determining the expression of one or more genes comprising a nucleic acid of one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified in class 424, subclass 6.

Groups 7058-8233. Claim 12 and 14, insofar as the claims are drawn to a method for inhibiting or neutralizing the activity or effect a polypeptide encoded a nucleic acid molecule, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of

SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified in class 435, subclass 183.

Groups 8234-9049. Claim 13, insofar as the claim is drawn to a method for treating carcinomas, said method comprising administering to a patient an inhibitor of a polypeptide encoded a nucleic acid molecule, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, which cannot be classified because the chemical and biologic nature of said inhibitor is not specified.

Groups 9050-10585. Claims 15 and 16, insofar as the claims are drawn to a polypeptide that specifically binds to a polypeptide encoded a nucleic acid molecule, wherein said nucleic acid molecule comprises one (1) of the polynucleotide sequences selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified, for example, in class 530, subclass 130.1.

Group 10586. Claim 17, drawn to a biochip comprising one or more nucleic acid segments consisting of a nucleic acid sequence selected from the group consisting the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, the mouse genomic, mRNA, and coding sequences as set froth in Tables 3-112, and the human genomic, mRNA and coding sequences as set forth in Tables 3-112, classified in class 422, subclass 82.08.

Group 10587. Claim 18, insofar as the claim is drawn to a method for diagnosing carcinomas comprising sequencing at least one CA gene of an individual, classified, for example, in class 435, subclass 6.

Group 10588. Claim 18, insofar as the claim is drawn to a method for determining a propensity to carcinomas comprising sequencing at least one CA gene of an individual, classified, for example, in class 435, subclass 6.

Group 10589. Claim 19, drawn to a method for determining CA gene copy number comprising adding one CA gene probe to a sample, classified, for example, in class 435, subclass 6.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups 1-1176 include both products and processes; the inventions of Groups 1177-2352, the inventions of Groups 9050-10585, and the inventions of Group 10586 are products; and the inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Group 7057, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10587, the inventions of Group 10588, and the inventions of Group 10589 are processes.

The inventions of Groups 1-1176 and the inventions of Groups 2353-9049 and 10587-10589 are unrelated because the products of Groups 1-1176 are not specifically used or otherwise involved in the processes of Groups 2353-9049 and 10587- 10589.

The inventions of Groups 1177-2352 and the inventions of Groups 2353-3528, 5881-7057, 8234-9049, and 10587- 10589 are unrelated because the products of Groups 1177-2352 are not specifically used or otherwise involved in the processes of Groups 2353-3528, 5881-7057, 8234-9049, and 10587- 10589.

The inventions of Groups 9050-10586 and the inventions of Groups 2353-9049 and 10587- 10589 are unrelated because the products of Groups 9050-10586 are not specifically used or otherwise involved in the processes of Groups 2353-9049 and 10587- 10589.

The inventions of Groups 1177-2352 and the inventions of Groups 3529-4704, respectively, are related as products and processes of use.

The inventions of Groups 1177-2352 and the inventions of Groups 4705-5880, respectively, are related as products and processes of use.

The inventions of Groups 1177-2352 and the inventions of Groups 7058-8233, respectively, are related as products and processes of use.

Inventions, which are related as products and processes of use, can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed, namely polypeptides can be used in a materially different process of using those products, such as the process of using any of the polypeptides as an immunogen to produce an antibody that binds specifically to the polypeptide.

The inventions of Groups 1177-2352 and any of the respective inventions of Groups 3529-5880 and 7058-8233 have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to the inventions of Groups 1177-2352 would not suffice to provide adequate information regarding the merit of the claims directed to any of the respective inventions of Groups 3529-5880 and 7058-8233, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be

performed to examine the inventions of Groups 1177-2352 and any of the respective inventions of Groups 3529-5880 and 7058-8233, an examination of more than one would constitute a serious burden.

Since the inventions of Groups 1177-2352 and any of the respective inventions of Groups 3529-5880 and 7058-8233 have been shown to be patentably distinct, and because the examination of more than one invention could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

Any of the inventions of Groups 1-1176 is patentably distinct from the others because each is either a different product or a materially different process. For example, the inventions of Group 1 are nucleic acid molecules, vectors comprising such nucleic acids, or host cells comprising such vectors, wherein the nucleic acid molecules comprise the polynucleotide sequence of SEQ ID NO: 1. The inventions of Group 1 also include methods for making the polypeptide encoded by this nucleic acid molecule. In contrast, the inventions of Group 953 are nucleic acid molecules, vectors comprising such nucleic acids, or host cells comprising such vectors, wherein the nucleic acid molecules comprise any of the polynucleotide sequences of SEQ ID NOs: 953-955 (i.e., the mouse genomic, mRNA, and coding sequences corresponding to the mouse *Fscn1* gene). The inventions of Group 953 also include methods for making the polypeptide encoded by this gene. Accordingly, the polynucleotide sequences of any of the inventions of Groups 1-1176 are different from the polynucleotide sequences of the others, and moreover the amino acid sequences of the polypeptides encoded by the polynucleotide sequences of any of the inventions of Groups 1-1176 are different from those encoded by the polynucleotide sequences of the others. Similarly, any of the inventions of Groups 1177-2352, any of the inventions of Groups 9050-10585, any of the inventions of Groups 2353-3528, any of the inventions of Groups 3529-4704, any of the inventions of Groups 4705-5880, any of the inventions of 5881-7056, any of the inventions of Groups 7058-8233, any of the inventions of Groups 8234-9049 are patentably distinct, each from the others, because each is either a different product (e.g., a polypeptide encoded by different polynucleotide sequences) or a materially different process (e.g., involving different cells comprising different nucleotide sequences encoding different polypeptides).

Because any of the inventions of Groups 1-1176, any of the inventions of Groups 1177-2352, any of the inventions of Groups 9050-10585, any of the inventions of Groups 2353-3528, any of the inventions of Groups 3529-4704, any of the inventions of Groups 4705-5880, any of the inventions of 5881-7056, any of the inventions of Groups 7058-8233, any of the inventions of Groups 8234-9049 are patentably distinct, each from the others, for these reasons, the search necessary to consider claims directed to any one of the inventions is not the same, nor is it coextensive with the search required to examine any of the others. For example, the search of claims directed to the invention of Group 1 require a search of relevant databases using SEQ ID NO: 1 as a query; in contrast, the search of claims directed to the invention of Group 1 require a search of relevant databases using at least one of SEQ ID NO: 953-955 as a query. Accordingly, different searches must be performed to examine claims directed to each different invention; and the need to perform more than one search would constitute a serious burden.

Since any of the inventions of Groups 1-1176, any of the inventions of Groups 1177-2352, any of the inventions of Groups 9050-10585, any of the inventions of Groups 2353-3528, any of the inventions of Groups 3529-4704, any of the inventions of Groups 4705-5880, any of the inventions of 5881-7056, any of the inventions of Groups 7058-8233, any of the inventions of Groups 8234-9049 are patentably distinct, each from the others, and because the examination of more than one of these inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups 1-1176, the inventions of Groups 1177-2352, the inventions of Groups 9050-10585, and the inventions of Group 10586 are patentably distinct for the following reasons:

The inventions of Groups 1-1176 are nucleic acid molecules, vectors comprising such nucleic acids, or host cells comprising such vectors, and methods for making the polypeptide encoded by such nucleic acid molecules. The inventions of Groups 1177-2352 are polypeptides. The inventions of Groups 9050-10585 are polypeptides that bind to particular polypeptide, such as antibodies. The inventions of Group 10586 are biochips.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of

nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups 1-1176 and the inventions of Groups 1177-2352 are patentably distinct products.

The inventions of Groups 1-1176 and the inventions of Groups 1177-2352 have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to any of the inventions of Groups 1-1176 would not suffice to provide adequate information regarding the merit of the claims directed to any of the inventions of Groups 1177-2352, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine any one the inventions of Groups 1-1176 and any one of the inventions of Groups 1177-

2352, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since any of the inventions of Groups 1-1176 and any of the inventions of Groups 1177-2352 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 1177-2352 and the invention of Groups 9050-10585, respectively, are patentably distinct because, although both are polypeptides, the inventions of Groups 1177-2352 are carcinoma-associated proteins, whereas the inventions of Groups 9050-10585, respectively, are proteins, such as antibodies, that bind to those different carcinoma-associated proteins. An antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, carcinoma-associated proteins is disclosed as consisting of a single polypeptide chain encoded by a single polynucleotide sequence; so the inventions of Groups 1177-2352 and the invention of Groups 9050-10585 are structurally distinct from one another. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody that binds a polypeptide

and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. In addition, the inventions of Groups 1177-2352 and the invention of Groups 9050-10585, as claimed, are functionally distinct. Therefore, the inventions of Groups 1177-2352 and the invention of Groups 9050-10585 are patentably distinct products.

Searching any one of the inventions of Groups 1177-2352 and any one of the invention of Groups 9050-10585 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search any one of the inventions of Groups 1177-2352 and any one of the inventions of Groups 9050-10585 would constitute a serious burden.

Since any of the inventions of Groups 1177-2352 and any of the invention of Groups 9050-10585 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 1-1176 and the inventions of Groups 9050-10585 are patentably distinct because a polynucleotide and a polypeptide, albeit a polypeptide not encoded by the polynucleotide that binds a polypeptide that is encoded by the polypeptide (e.g., an antibody) are chemically distinct molecules, since a polynucleotide is composed of polymers of nucleotides, whereas antibodies are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the

nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, inventions of Groups 1-1176 and the inventions of Groups 9050-10585 are patentably distinct products.

Searching any of the inventions of Groups 1-1176 and any of the inventions of Groups 9050-10585 would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search any of the inventions of Groups 1-1176 and any of the inventions of Groups 9050-10585 would constitute a serious burden.

Since any of the inventions of Groups 1-1176 and any of the inventions of Groups 9050-10585 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Group 10586, which are biochips, are patentably distinct from the inventions of Groups 1-1176 (i.e., nucleic acid molecules, vectors comprising such nucleic acids, or host cells comprising such vectors, and methods for making the polypeptide encoded by such nucleic acid molecules), the inventions of Groups 1177-2352 (i.e., polypeptides), and the inventions of Groups 9050-10585 (i.e., polypeptides that bind to particular polypeptide, such as antibodies). In marked contrast to the compositions and structures of nucleic acid molecules, vectors, host cells, polypeptides, and antibodies, for example, a biochip is generally an article of manufacture composed of a composite of inorganic and organic materials onto which is arrayed a plurality of different molecules, which, in this instance, are nucleic acid molecules comprising different sequences. Accordingly, any relationship that exists between the biochips of Group 10586 and any one or more of the inventions of Groups 1-1176 depends upon whether or not the biochip comprises the polynucleotide sequence of the nucleic acid molecules of Groups 1-1176. However, a biochip generally does not comprise a single nucleic acid molecule; rather it may comprise more than a million distinct nucleic acids. As such, any relationship between any of the biochips of Group 10586 and any one or more of the inventions of Groups 1-1176 is not an exclusive relationship, since any given biochip may comprise a different plurality of nucleic acid

sequences, which may include some, but not necessarily all of the nucleic acid sequences arrayed on another. Additionally, the inventions of Group 10586 and the inventions of Groups 1-1176 are patentably distinct products, despite any such relationship, since biochips and nucleic acid molecules are compositionally and structurally distinct, and made by a different processes. Lastly, in further contrast to the polynucleotides of the inventions of Groups 1-1176, a biochip does not necessarily comprise the entire coding sequence of a gene; rather it more generally comprises only an identifiable segment of the nucleotide sequence of a gene.

The inventions of Group 10586 and any of the inventions of Groups 1-1176, 1177-2352, and 9050-10585 have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide, polypeptide, or antibody, for example, is a different from the search performed in examining claims drawn to a biochip. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to the inventions of Group 10586 would not suffice to provide adequate information regarding the merit of the claims directed to any of the inventions of Groups 1-1176, 1177-2352, and 9050-10585, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Group 10586 and any one of the inventions of Groups 1-1176, 1177-2352, and 9050-10585, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Group 10586 and the inventions of any one of Groups 1-1176, 1177-2352, and 9050-10585 are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups 1-1176, the inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Group 7057, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10587, the inventions of Group 10588, and the inventions of Group 10589 are patentably distinct for the following reasons:

The inventions of Groups 1-1176 are methods for making a polypeptide; the inventions of Groups 2353-3528 are methods for screening drug candidates, the inventions of Groups 3529-4704 are methods for screening bioactive agents that bind to a protein, the inventions of Groups 4705-5880 are methods for screening bioactive agents that modulate the activity of a protein, the inventions of 5881-7056 are methods for evaluating the effect of a drug *in vivo*, the inventions of Groups 7057 and 10587 are methods for diagnosing carcinomas, the inventions of Groups 7058-8233 are methods for neutralizing the activity of a protein *in vitro*, the inventions of Groups 8234-9049 are methods for treating carcinomas, the inventions of Group 10588 are methods for determining a propensity to develop carcinomas, and the inventions of Group 10589 are methods for determining CA gene copy number.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. See MPEP §§ 806.04 and 808.01. The instant specification does not appear to disclose that any of the inventions of Groups 1-1176, any of inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Groups 7057 and 10587, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10587, the inventions of Group 10588, and the inventions of Group 10589 are useable together. Therefore, because the inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Groups 7057 and 10587, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10588, and the inventions of Group 10589 have different purposes, the inventions appear unrelated.

If not unrelated, the inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Group 7057, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10587, the inventions of Group 10588, and the inventions of Group 10589 are patentably distinct, each from the others, for the following reasons:

Again, the inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Groups 7057 and 10587, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10588, and the inventions of Group 10589 have different purposes or objectives. Besides having different objectives, any of the inventions of Groups 2353-3528, any of the inventions of Groups 3529-4704, any of the inventions of Groups 4705-5880, any of the inventions of 5881-7056, any of the inventions of Groups 7057 and 10587, any of the inventions of Groups 7058-8233, any of the inventions of Groups 8234-9049, any of the inventions of Group 10588, and any of the inventions of Group 10589 are patentably distinct from the others because each is a materially different processes comprising different process steps. Furthermore, because each has a different objective each necessarily has different criteria for success and in general involves the measurement of different endpoints and the establishment of different relationships or correlations.

Although the inventions of Groups 7057 and 10587 share the same purpose or objective, they are nonetheless patentably distinct inventions because they are materially different processes comprising different process steps. The inventions of Group 7057 comprise determining the expression of one or more genes; in contrast, the inventions of Group 10587 comprise sequencing at least one CA gene. Furthermore, because each is a different process, each necessarily has different criteria for success; and moreover each involves the measurement of a different endpoint and therefore necessarily involves the establishment of different relationships or correlations.

Because the inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Group 7057, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10587, the inventions of Group 10588, and the inventions of Group 10589 are patentably

distinct, each from the others, for these reasons, the search necessary to consider claims directed to any one of the inventions is not the same, nor is it coextensive with the search required to examine any of the others. Accordingly, different searches must be performed to examine claims directed to each different invention; and the need to perform more than one search would constitute a serious burden.

Since the inventions of Groups 2353-3528, the inventions of Groups 3529-4704, the inventions of Groups 4705-5880, the inventions of 5881-7056, the inventions of Group 7057, the inventions of Groups 7058-8233, the inventions of Groups 8234-9049, the inventions of Group 10587, the inventions of Group 10588, and the inventions of Group 10589 are patentably distinct, each from the others, and because the examination of more than one of these inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

6. This application contains claims 11 and 17 directed to patentably distinct species of the claimed invention. Applicant is required to elect a species of the invention of Groups 7057 and 10586 by specifically identifying one or more of the polynucleotide sequence, wherein said polynucleotide sequences are selected from the group consisting of (a) the "mouse tags" of SEQ ID NOs: 1-952, as set forth in Table 1 or Table 2, (b) the mouse genomic, mRNA, and coding sequences as set forth in Tables 3-112, and (c) the human genomic, mRNA and coding sequences as set forth in Tables 3-112.

Each species of inventions is patentably distinct from the others since each member of the polynucleotide sequences of products is distinct from the others because each (for example) has a unique nucleic acid sequence that differs from the others. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required

for examination of any of the other species of invention, because the search of any one member of the polynucleotide sequence of products will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one product to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chanda L. Macias, Ph.D. whose telephone number is (571) 272-9032. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chanda L. Macias, Ph.D.
Examiner
Art Unit 1643

STEPHEN RAWLINGS
PRIMARY EXAMINER
ART UNIT 1643

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